IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

----------x

JEFFREY DEFOREST and VICKIE DEFOREST

Plaintiffs,

Case No. 14-cv-2405

COMPLAINT
AND JURY DEMAND

-against-

AbbVie Inc., and Abbott Laboratories, Inc.,

Defendants.

----------x

Plaintiffs, by their attorneys, **DOUGLAS & LONDON, P.C. and SCHLICHTER. BOGARD and DENTON**, upon information and belief, at all times hereinafter mentioned, allege as follows:

PROCEDURAL AND FACTUAL BACKGROUND

1. This case involves the prescription drug Androgel, which is manufactured, sold, distributed and promoted by the Defendants AbbVie, Inc. and Abbott Laboratories Inc. (hereinafter jointly "Defendants" or "AbbVie") as a testosterone replacement therapy.

2. Defendants misrepresented that AndroGel is a safe and effective treatment of hypogonadism and a condition they referred to as "low testosterone," when in fact the drug causes serious medical problems, including life threatening cardiac events, strokes and thrombolytic events.

3. AndroGel causes the hematocrit level to increase, thereby thickening the blood. This effect, if not monitored and controlled properly, can lead to life threatening cardiac events, strokes and thrombolyctic events.

4. Defendants failed to adequately warn physicians about the risks associated with AndroGel and the monitoring required to ensure their patient's safety.

5. Defendants engaged in aggressive, award-winning direct to consumer and physician marketing and advertising campaigns for AndroGel. Further, Defendants engaged in an aggressive unbranded "disease awareness" campaign to alert men that they might suffering from "low T" or "low testosterone."

6. According to the industry-leading Androgen Deficiency in Adult Males ("ADAM") or "Is it Low T?" quiz, the symptoms of "Low T" include being "sad or grumpy," "experiencing deterioration in the ability to play sports," and "falling asleep after dinner." Available at: http: www.isitlowt.com/do-you-have-low-t.low-t-quiz. Most doctors agree that these symptoms can be caused by an abundance of factors, the most prominent of which is the natural aging process.

7. As a result of this "disease mongering," as termed by Dr. Adriane Fugh-Berman of Georgetown University Medical Center, diagnoses of "Low T" have increased exponentially. This has directly related to AndroGel's sales increasing to over $1.37 billion per year.

8. However, consumers of AndroGel were mislead as to the drug's safety and efficacy, and as a result have suffered injuries including life-threatening cardiac events, strokes and thrombolytic events.

PARTIES

9. Plaintiff Jeffrey Deforest is a citizen and resident of the state of Tennessee.

10. Plaintiff Jeffrey Deforest was born September 26, 1964.

10. Plaintiff Jeffery Deforest began using AndroGel in approximately December 2012 and used it regularly thereafter.

11. As a result of Defendants' AndroGel, Plaintiff Jeffrey Deforest was caused to suffer from a heart attack, on April 15, 2013, underwent surgical intervention and was prescribed a medication regimen.

12. Plaintiff incurred significant medical expenses as a result of his treatment, will incur future medical expenses, his ability to earn money has been impaired and he is at an increased risk for future health problems and disability, and he suffered physical pain and mental anguish.

13. The injuries and damages sustained by Plaintiff Jeffrey Deforest were caused by Defendants' AndroGel.

14. Plaintiff Vickie Deforest is a citizen and resident of the state of Tennessee.

15. At all relevant times, Plaintiff Jeffrey Deforest and Plaintiff Vickie Deforest were and still are husband and wife.

16. Defendant AbbVie is a corporation organized and existing under the laws of Delaware with its principal place of business at 1 North Waukegan Road, North Chicago, Lake County, Illinois 60064.

17. Defendant Abbott Laboratories Inc. is a corporation organized under the laws of the state of Illinois and maintains its principal place of business at 100 Abbott Park Road, North Chicago, Lake County, Illinois 60064.

18. By way of background, Unimed Pharmaceuticals Inc. originally developed AndroGel and sought FDA approval in 1999. Before the drug was approved by the FDA in 2000, Solvay Pharmaceuticals, Inc. acquired Unimed Pharmaceuticals, Inc. and subsequently bought AndroGel to market. In 2010, Defendant Abbott Laboratories, Inc., acquired Solvay's pharmaceutical division which included AndroGel. Then in 2013, Abbott created AbbVie, a

company composed of Abbott's former proprietary pharmaceutical business, which included AndroGel.

JURISDICTION AND VENUE

19. This Court has jurisdiction over Defendants and this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between Plaintiffs and Defendants and because the amount in controversy between Plaintiffs and Defendants exceeds $75,000, exclusive of interest and cost, and because, among other reasons, Defendants have significant contacts with this district by virtue of doing business within this judicial district.

20. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391 because the Defendants have their primary place of business in this district.

21. Venue is also proper in this judicial district pursuant to 28 U.S.C. §1391 because, *inter alia*, a substantial part of the events or omissions giving rise to the Plaintiff's claims occurred in, and because the Defendants transact business in, this district.

FACTUAL ALLEGATIONS

22. This actions is for damages brought on behalf of Plaintiff Jeffrey Deforest who was prescribed and supplied, received and who has taken and applied the prescription drug AndroGel, as tested, studied, researched, evaluated, endorsed, designed, formulated, compounded, manufactured, produced, processed, assembled, inspected, distributed, marketed, labeled, promoted, packaged, advertised for sale, prescribed, sold or otherwise placed in the stream of interstate commerce by Defendants. This action seeks, among other relief, general and special damages and equitable relief in order to enable the Plaintiff to treat and monitor the dangerous, severe and life-threatening side effects caused by this drug.

23. Defendants' wrongful acts, omissions and fraudulent representations caused Plaintiff's injuries and damages.

24. At all relevant times herein mentioned, the Defendants were engaged in the business of, or were successors in interest to, entities engaged in the business of research, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging and/or advertising for sale or selling the prescription drug AndroGel for the use and application by men, including, but not limited to Plaintiff Jeffrey Deforest.

25. At all times herein mentioned, Defendants were authorized to do business within the states of Tennessee and Illinois.

26. At all times herein mentioned, the officers and directors of Defendants participated in, authorized, and directed the production and promotion of the aforementioned product when they knew, or with the exercise of reasonable care should have known, of the hazards and dangerous propensities of said product and thereby actively participated in the tortious conduct which resulted in the injuries suffered by the Plaintiff herein.

27. Hypogonadism is a specific and recognized condition of the endocrine system, which in men may involve the severely diminished production or nonproduction of testosterone.

28. In 1999, when Unimed Pharmaceuticals Inc., one of the Defendants' predecessor companies, asked for FDA approval of AndroGel, it asserted that hypogonadism was estimated to affect approximately "one million American men."

29. In 2000, when the FDA approved AndroGel, the company announced that the market was "four to five million American men." By 2003, the number increased to "up to 20 million men." However, a study published in the Journal of American Medical Association

("JAMA") in August 2013 entitled "Trends in Androgen Prescribing in the United States, 2001-2011" indicated that many men who get testosterone prescriptions have no evidence of hypogonadism. For example, one third of men prescribed testosterone had a diagnosis of fatigue, and one quarter of men did not even have their testosterone levels tested before they received a testosterone prescription.

30. Defendants coordinated a massive advertising campaign designed to convince men that they suffered from low testosterone. Defendants orchestrated a national disease awareness media blitz that purported to educate male consumers about the signs of low testosterone. The marketing campaign consisted of television advertisements, promotional literature placed in healthcare providers' offices and distributed to potential AndroGel users, and online media including the unbranded website "IsItLowT.com."

31. The television advertisements suggest that various symptoms often associated with other conditions may be caused by low testosterone and encourage men to discuss testosterone replacement therapy with their doctors if they experienced any of the "symptoms" of low testosterone. These "symptoms" include listlessness, increased body fat, and moodiness - all general symptoms that are often a result of aging, weight gain or lifestyle, rather than low testosterone.

32. Defendants' national education campaign included the creation and continued operation of the website www.IsItLowT.com. The website asserts that millions of otherwise healthy men experience low testosterone and encourages male visitors to "Take the 'Is it Low T' Quiz." The "Is it Low T" quiz asks men if they have experienced potential signs of low testosterone, including "Have you experienced a recent deterioration in your ability to play

sports?", "Are you falling asleep after dinner?", "Are you sad and/or grumpy?" and "Do you have a lack of energy?"

33. Dr. John Morley, director of endocrinology and geriatrics at St. Louis University School of Medicine, developed this quiz at the behest of Dutch pharmaceutical company Organon BioSciences, in exchange for $40,000 grant to this university. The pharmaceutical company instructed Dr. Morley, "Don't make it too long and make it somewhat sexy." Dr. Morley drafted the questionnaire in 20 minutes in the bathroom, scribbling the questions on toilet paper and giving them to his secretary the next day to type up. Dr. Morley admits that he has "no trouble calling it a crappy questionnaire" and that it is "not ideal." This is the "Low T Quiz" used on the "IsItLowT" website. Natasha Singer, *Selling that New-Man Feeling*, Nov. 23 2013, N.Y. TIMES.

34. Since the FDA approved AndroGel, Defendants have also sought to convince primary care physicians that low testosterone levels are widely under-diagnosed, and that conditions associated with normal aging could be caused by low testosterone levels.

35. While running its disease awareness campaign, Defendants promote their product AndroGel as an easy to use topical testosterone replacement therapy. Defendants contrast their product's at-home topical application with less convenient prescription testosterone injections, which require frequent doctor visits.

36. Defendants convinced millions of men to discuss testosterone replacement therapy with their doctors, and consumers and their physicians relied on Defendants' promises of safety and ease. Although prescription testosterone replacement therapy had been available for years, millions of men who had never been prescribed testosterone flocked to their doctors and pharmacies.

37. What consumers received, however, were not safe drugs but a product which causes life-threatening problems, including strokes, heart attacks, pulmonary embolisms and blood clots.

38. Defendants successfully created robust and previously nonexistent market for their drug. Defendant Abbott Laboratories spent $80 million promoting AndroGel in 2012. The company also spent millions on its unbranded marketing including commercials and its websites, www.IsItLowT.com and www.DriveForFive.com, sites which recommend that men have regular checkups with their physicians and five regular tests done: including cholesterol, blood pressure, blood sugar, prostate-specific antigen and testosterone.

39. Defendants' advertising paid off in a return of $1.4 billion in sales during the past year, making AndroGel the biggest selling androgen drug in the United States. Sales of replacement therapies have more than doubled since 2006, and are expected to triple to $5 billion by 2017, according to forecasts by Global Industry Analysts. Shannon Pettypiece, *Are Testosterone Drugs the Next Viagra*?, May 10, 2012, Bloomberg Business Week, *available at*: http://www.businessweek.com/articles/2012-05-10/are-testosterone-drugs-the-next-viagra.

40. In early 2013, Medical Marketing & Media named two AbbVie executives as "the all-start large pharma marketing team of the year" for promotions of AndroGel and unbranded efforts to advance low T. *See* Singer, *Selling That New-Man Feeling*, *supra*; *See also*, Larry Dobrow, *All-star large pharma marketing team of the year: Androgel*. Jan. 2, 2013, Medical Marketing & Media, available at: http://www.mmm-online.com/all-star-large-pharma-marketing-team-of-the-year-androgel/article/273242/.

41. The marketing program sought to create the image and belief by consumers and physicians that low testosterone affected a large number of men in the United States and that the

use of AndroGel is safe for human use, even though Defendants knew these to be false, and even though Defendants had no reasonable grounds to believe them to be true.

42. There have been a number of studies associating testosterone use in men with an increased risk of heart attacks and strokes.

43. In 2010, a New England Journal of Medicine Study entitled "Adverse Events Associated with Testosterone Administration" was discontinued after an exceedingly high number of men in the testosterone group suffered adverse events.

44. In November 2013, a JAMA study was released entitled "Association of Testosterone Therapy with Mortality, Myocardial Infarction, and Stroke in Men with Low Testosterone Levels" which indicated that testosterone therapy raised the risk of death, heart attack and stroke by about 30%.

45. On January 29, 2014, a study was released in PLOS ONE entitled "Increased Risk of Non-Fatal Myocardial Infarction Following Testosterone Therapy Prescription in Men" which indicated that testosterone use doubled the risk of heart attacks in men over sixty five years old and men younger than sixty five with a previous diagnosis of heart disease.

46. On February 28, 2000, when the FDA approved AndroGel 1%, it was approved for the treatment of adult males, who have low or no testosterone (AndroGel 1.62% was approved in April, 2011). After FDA approval, AndroGel was widely advertised and marketed by Defendants as safe and effective testosterone replacement therapy,

47. AndroGel is a hydroalcoholic gel containing testosterone either 1% or 1.62%, applied to the chest, arms or stomach and enters the body through transdermal absorption. The AndroGel 1.62% product also contains isopropyl myristate as an ointment and ethanol for absorption enhancement.

48. Testosterone is the primary androgenic hormone responsible for normal growth, development of the male sex organs, and maintenance of secondary sex characteristics.

49. The hormone plays a role in sperm production, fat distribution, maintenance of muscle strength and mass and sex drive.

50. In men, testosterone levels normally begin a gradual decline after the age of thirty.

51. The average testosterone levels for most men range from 300 to 1,000 nanograms per deciliter of blood. However, testosterone levels can fluctuate greatly depending on many factors, including sleep, time of day, and medication. Resultantly, many men who may have testosterone levels below 300 ng/dl on one day will have normal testosterone levels the next.

52. AndroGel may produce undesirable side effects to patients who use the drug including but not limited to myocardial infarction, stroke, pulmonary embolism and death.

53. In some patient populations, AndroGel use may increase the incidence of adverse events and death by over 500%.

54. In addition to the above, AndroGel has been linked to several severe and life changing medical disorders in both users and those who come into physical contact with users or the unwashed clothes of someone who applied AndroGel. Patients taking AndroGel may experience enlarged prostates and increased serum prostate-specific antigen levels.

55. Secondary exposure to AndroGel can cause side effects in others. In 2009, the FDA issued a black box warning for AndroGel prescriptions, advising patients of reported virilization in children who were secondarily exposed to the gel. Testosterone may also cause physical changes in women exposed to the drug and cause fetal damage with pregnant women who come into secondary contact with AndroGel.

56. Defendants' marketing strategy beginning in 2000 has been to aggressively market and sell their products by misleading potential users about the prevalence and symptoms of low testosterone and by failing to protect users from serious dangers that Defendants knew or should have known result from use of its products.

57. Defendants successfully marketed AndroGel by undertaking a "disease awareness" marketing campaign. This campaign sought to create a consumer perception that low testosterone is prevalent amount U.S. men and that symptoms previously associated with other physical and mental conditions, such as aging, stress, depression and lethargy were actually attributable to "Low-T."

58. AbbVie's advertising program, sought to create the image and belief by consumers and their physicians that that the use of AndroGel was a safe method of alleviating their systems, had few side effects and would not interfere with their daily lives, even though Defendants knew or should have known these to be false, and even though the Defendants had no reasonable grounds to believe them to be true.

59. Defendants purposefully downplayed, understated and outright ignored the health hazards and risk associated with using AndroGel. Defendant deceived potential AndroGel users by relaying position information through the press, including testimonials from retired professional athletes, and manipulating hypogonadism statistics to suggest widespread disease prevalence, while downplaying known adverse and serious health effects.

60. Defendants concealed material relevant information from potential AndroGel users and minimized user and prescriber concern regarding the safety of AndroGel.

61. In particular, in the warnings Defendants give in their commercials, online and print advertisements, Defendants fail to mention any potential risk of cardiac event, stroke,

pulmonary embolism or other dangerous side effects related to blood clotting and falsely represents that AbbVie adequately tested AndroGel for all likely side effects. The Defendants also fail to warn and instruct regarding the importance of adequate monitoring of hematocrit levels.

62. As a result of Defendants' advertising and marketing, and representations about its product, men in the United States pervasively seek out prescriptions for AndroGel. If Plaintiff had known the risks and dangers associated with AndroGel, the Plaintiff would not have taken AndroGel and consequently would not have been subject to its serious side effects.

FIRST CAUSE OF ACTION
AS AGAINST DEFENDANTS
(NEGLIGENCE AND NEGLIGENCE PER SE)

63. Plaintiffs repeat, reiterate and re-allege each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

64. Defendants had a duty to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale and/or distribution of AndroGel into the stream of commerce, including a duty to assure that the product would not cause users to suffer unreasonable, dangerous side effects.

65. Defendants failed to exercise ordinary care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of AndroGel into interstate commerce in that Defendants knew or should have known that using AndroGel placed users at risk for developing serious and dangerous side effects including but not limited to, heart attacks, strokes, pulmonary embolisms,

cardiovascular events and blood clots, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

66. The negligence of the Defendants, their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

a. Manufacturing, producing, promoting, formulating, creating, and/or designing AndroGel without thoroughly testing it;

b. Manufacturing, producing, promoting, formulating, creating, and/or designing AndroGel without adequately testing it;

c. Not conducting sufficient testing programs to determine whether or not the aforesaid AndroGel was safe for use; in that Defendants herein knew or should have known that AndroGel was unsafe and unfit for use by reason of the dangers to its users;

d. Selling AndroGel without making proper and sufficient tests to determine the dangers to its users;

e. Negligently failing to adequately and correctly warn the Plaintiff, the public, the medical and healthcare profession, and/or the FDA of the dangers of AndroGel;

f. Negligently failing to recall its dangerous and defective AndroGel at the earliest date that it became known that AndroGel was, in fact, dangerous and defective;

g. Failing to provide adequate instructions regarding safety precautions to be observed by users, handlers, and persons who would reasonably and foreseeably come into contact with, and more particularly, use, AndroGel;

h. Failing to test AndroGel and/or failing to adequately, sufficiently and properly test AndroGel;

i. Negligently advertising and recommending the use of the aforesaid AndroGel without sufficient knowledge as to its dangerous propensities;

j. Negligently representing that AndroGel was safe for use for its intended purpose, when, in fact, it was unsafe;

k. Negligently representing that Androgel had equivalent safety and efficacy as other testosterone replacement products;

l. Negligently designing AndroGel in a manner which was dangerous to its users;

m. Negligently manufacturing AndroGel in a manner which was dangerous to its users;

n. Negligently producing AndroGel in a manner which was dangerous to its users;

o. Negligently assembling AndroGel in a manner which was dangerous to its users;

p. Concealing information concerning tests, and/or reports, and/or studies from the Plaintiff showing that AndroGel was unsafe, dangerous, and/or non-conforming with accepted industry standards;

q. Improperly concealing and/or misrepresenting information from the Plaintiff, healthcare professionals, and/or the public, concerning the severity of risks and dangers of AndroGel.

r. Defendants violated statutes, rules and ordinates concerning the manufacturing, marketing, and/or testing of their product.

67. Defendants under-reported, underestimated and downplayed the serious danger of AndroGel.

68. Defendants were negligent in the designing, researching, supplying, manufacturing, promoting, packaging, distributing, testing, advertising, warning, marketing and sale of AndroGel in that they:

a. Failed to use due care in designing and manufacturing AndroGel so as to avoid the aforementioned risks to individuals when AndroGel was used for its intended purpose.

b. Failed to accompany their product with proper warnings regarding all possible adverse side effects concerning the use of AndroGel;

c. Failed to accompany their product with proper and/or accurate warnings regarding all possible adverse side effects associated with the use of AndroGel;

d. Failed to warn Plaintiff of the severity and duration of such adverse effects, as the warnings given did not accurately reflect the symptoms, or severity of the side effects;

e. Failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of AndroGel;

f. Failed to warn Plaintiff, prior to actively encouraging the sale of AndroGel, either directly or indirectly, orally or in writing, about the need for more comprehensive, more regular medical monitoring than usual to ensure early discovery of potentially serious side effects; and

g. Were otherwise careless and/or negligent.

69. Despite the fact that Defendants knew or should have known that AndroGel caused unreasonably dangerous side effects, Defendants continued to market, manufacture, distribute and/or sell AndroGel to consumers, including the Plaintiff.

70. Defendants' actions, by violating statutes, ordinances and/or rules and regulations, constituted negligence per se.

71. Defendants knew or should have known that consumers such as the Plaintiff would foreseeably suffer injury, and/or be at increased risk of suffering injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

72. Defendants' negligence was the proximate cause of Plaintiff's injuries, harm and economic loss which they suffered and/or will continue to suffer.

73. By reason of the foregoing Plaintiff Jeffrey Deforest experienced and/or is at risk of experiencing serious and dangerous side effects including but not limited to, heart attacks, strokes, pulmonary embolisms, cardiovascular events and blood clots, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment,

monitoring and/or medications, and fear of developing any of the above named health consequences.

74. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further allege that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

75. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

SECOND CAUSE OF ACTION
AS AGAINST DEFENDANTS
(STRICT PRODUCTS LIABILITY)

76. Plaintiffs repeat, reiterate and re-allege each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

77. At all times herein mentioned, the Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed AndroGel as hereinabove described that was used by Plaintiff.

78. That AndroGel was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by the Defendants.

79. At those times, the AndroGel was in an unsafe, defective, and inherently dangerous condition, which was dangerous to users, and in particular, Plaintiff Jeffrey Deforest.

80. The AndroGel designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective in design or formulation in that,

when it left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation of the aforesaid AndroGel.

81. At all times herein mentioned, the AndroGel was in a defective condition and unsafe, and Defendants knew or had reason to know that said products were defective and unsafe, especially when used in the form and manner as provided by the Defendants.

82. Defendants knew, or should have known, that at all times herein mentioned its AndroGel was in a defective condition, and were and are inherently dangerous and unsafe.

83. At the time of the Plaintiff's use of the AndroGel, the aforesaid product was being used for the purposes and in a manner normally intended, namely for the treatment of Low T.

84. Defendants with this knowledge voluntarily manufactured AndroGel in a dangerous condition for use by the public, and in particular the Plaintiff Jeffrey Deforest.

85. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, intended use.

86. AndroGel designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was manufactured defectively in that said products left the hands of Defendants in a defective condition and were unreasonably dangerous to their intended users.

87. The AndroGel designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants reached its intended users in the same defective and unreasonably dangerous condition in which the Defendants' products was manufactured.

88. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which created an unreasonable risk to the

health of consumers and to Plaintiff Jeffrey Deforest, in particular, and Defendants are therefore strictly liable for the injuries sustained by the Plaintiff.

89. The Plaintiff could not, by the exercise of reasonable care, discover the defective nature of using the AndroGel herein mentioned and perceived its danger.

90. The AndroGel designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate warnings or instructions as the Defendants knew or should have known that the product created a risk of serious and dangerous side effects including but not limited to pain, heart attacks, strokes, pulmonary embolisms, cardiovascular events and blood clots, and/or other severe and permanent health consequences.

91. The AndroGel designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate warnings and/or inadequate testing.

92. The AndroGel designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate post-marketing surveillance and/or warnings because, after Defendants knew or should have known of the risks of serious side effects including but not limited to pain, heart attacks, strokes, pulmonary embolisms, cardiovascular events and blood clots, and/or other severe and permanent health consequences.

93. By reason of the foregoing, the Defendants have become strictly liable in tort to the Plaintiff for the manufacturing, marketing, promoting, distribution, and selling of AndroGel.

94. Defendants' defective design, manufacturing defect, and inadequate warnings for AndroGel were acts that amount to willful, wanton, and/or reckless conduct by Defendants.

95. By reason of the foregoing Plaintiff has experienced and/or is at risk of experiencing serious and dangerous side effects including but not limited to, heart attacks, strokes, pulmonary embolisms, cardiovascular events and blood clots, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

96. As a result of the foregoing acts and omissions Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believe and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

97. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

THIRD CAUSE OF ACTION
AS AGAINST ALL DEFENDANTS
(BREACH OF EXPRESS WARRANTY)

98. Plaintiffs repeat, reiterate and re-allege each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

99. Defendants expressly warranted that AndroGel was safe and well accepted by users.

100. The AndroGel does not conform to these express representations because it is not safe and has numerous serious side effects, many of which were not accurately warned about by Defendants. As a direct and proximate result of the breach of said warranties, Plaintiff suffered

and/or will continue to suffer, and/or is at increased risk to suffer severe and permanent personal injuries, harm and/or economic loss.

101. Plaintiff did rely on the express warranties of the Defendants herein.

102. Members of the medical community, including physicians and/or other healthcare professionals, relied upon the representations and warranties of the Defendants for use of AndroGel in recommending and/or dispensing it.

103. The Defendants herein breached the aforesaid express warranties, as its AndroGel was defective.

104. Defendants expressly represented to Plaintiff, and/or his physicians, healthcare providers that AndroGel was safe and fit for use for the purposes intended, that it was of merchantable quality, that it did not produce any dangerous side effects in excess of those risks associated with other, non-defective testosterone products, that the side effects it did produce were accurately reflected in the warnings and that it was adequately tested and fit for its intended use.

105. Defendants knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that AndroGel is not safe and fit for the use intended, and, in fact, produced serious injuries to the users that were not accurately identified and represented by Defendants.

106. By reason of the foregoing Plaintiff has experienced and/or is at risk of experiencing serious and dangerous side effects including but not limited to, heart attacks, strokes, pulmonary embolisms, cardiovascular events and blood clots, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment,

monitoring and/or medications, and fear of developing any of the above named health consequences.

107. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believe and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

108. By reason of the foregoing, Plaintiffs have been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

FOURTH CAUSE OF ACTION
AS AGAINST ALL DEFENDANTS
(BREACH OF IMPLIED WARRANTIES)

109. Plaintiffs repeat, reiterate and re-allege each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

110. At all times herein mentioned, Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold AndroGel for the treatment of Low T.

111. At the time Defendants marketed, sold, and distributed AndroGel for use by Plaintiff, Defendants knew of the use for which AndroGel was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

112. Defendants impliedly represented and warranted to the users of AndroGel and/or their physicians, healthcare providers, and/or the FDA that AndroGel was safe and of merchantable quality and fit for the ordinary purpose for which said product was to be used.

113. That said representations and warranties aforementioned were false, misleading, and inaccurate in that AndroGel was unsafe, unreasonably dangerous, improper, not of merchantable quality, and defective.

114. Plaintiff and/or members of the medical community and/or healthcare professionals did rely on said implied warranty of merchantability of fitness for a particular use and purpose.

115. Plaintiff and/or his physicians and/or healthcare professionals reasonably relied upon the skill and judgment of Defendants as to whether AndroGel was of merchantable quality and safe and fit for its intended use.

116. AndroGel was injected into the stream of commerce by the Defendants in a defective, unsafe, and inherently dangerous condition and the products and materials were expected to and did reach users, handlers, and persons coming into contact with said products without substantial change in the condition in which they were sold.

117. The Defendants herein breached the aforesaid implied warranties, as AndroGel was not fit for its intended purposes and uses.

118. By reason of the foregoing Plaintiff has experienced and/or is at risk of experiencing serious and dangerous side effects including but not limited to, heart attacks, strokes, pulmonary embolisms, cardiovascular events and blood clots, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

119. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

120. By reason of the foregoing, Plaintiffs have been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

FIFTH CAUSE OF ACTION
AS AGAINST ALL DEFENDANTS
(FRAUDULENT MISREPRESENTATION)

121. Plaintiffs repeat, reiterate and re-allege each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

122. The Defendants falsely and fraudulently represented to the medical and healthcare community and to the Plaintiff and/or the FDA, and/or the public in general, that AndroGel, had been tested and was found to be safe and/or effective for the treatment of Low T.

123. That representations made by Defendants were, in fact, false.

124. When said representations were made by Defendants, they knew those representations to be false and they willfully, wantonly and recklessly disregarded whether the representations were true.

125. These representations were made by said Defendants with the intent of defrauding and deceiving the Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, to recommend, dispense and/or purchase AndroGel, for

treatment of Low T, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of the Plaintiff.

126. At the time the aforesaid representations were made by the Defendants and, at the time the Plaintiff used AndroGel, the Plaintiff was unaware of the falsity of said representations and reasonably believed them to be true.

127. In reliance upon said representations, the Plaintiff was induced to and did use AndroGel, thereby sustaining severe and permanent personal injuries, and/or being at an increased risk of sustaining severe and permanent personal injuries in the future.

128. Said Defendants knew and were aware or should have been aware that AndroGel had not been sufficiently tested, was defective in nature, and/or that it lacked adequate and/or sufficient warnings.

129. Defendants knew or should have known that AndroGel had a potential to, could, and would cause severe and grievous injury to the users of said product, and that they were inherently dangerous in a manner that exceeded any purported, inaccurate, and/or down-played warnings.

130. Defendants brought AndroGel to the market, and acted fraudulently, wantonly and maliciously to the detriment of the Plaintiff.

131. By reason of the foregoing Plaintiff has experienced and/or is at risk of experiencing serious and dangerous side effects including but not limited to, heart attacks, strokes, pulmonary embolisms, cardiovascular events and blood clots, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment,

monitoring and/or medications, and fear of developing any of the above named health consequences.

132. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believe and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

133. By reason of the foregoing, Plaintiffs have been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

SIXTH CAUSE OF ACTION
AS AGAINST ALL DEFENDANTS
(FRAUDULENT CONCEALMENT)

134. Plaintiffs repeat, reiterate and re-allege each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

135. At all times during the course of dealing between Defendants and Plaintiff and/or Plaintiff's healthcare providers, and/or the FDA, Defendants misrepresented the safety of AndroGel for its intended use.

136. Defendants knew or were reckless in not knowing that its representations were false.

137. In representations to Plaintiff and/or Plaintiff's healthcare providers and/or the FDA, Defendants fraudulently concealed and intentionally omitted the following material information:

a. That AndroGel was not as safe as other available testosterone replacement products;

b. That the risks of adverse events with AndroGel was higher than those with other available testosterone replacement products;

c. That the risks of adverse events with AndroGel was not adequately tested and/or known by Defendants;

d. Plaintiff was put at risk of experiencing serious and dangerous side effects including but not limited to, heart attacks, strokes, pulmonary embolisms, cardiovascular events and blood clots, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish;

e. That patients needed to be monitored more regularly than normal while using AndroGel;

f. That AndroGel was manufactured, marketed, produced, and distributed negligently;

g. That AndroGel was manufactured, marketed, produced, and distributed negligently;

h. That AndroGel was manufactured, marketed, produced, and distributed negligently;

i. That AndroGel was designed negligently;

j. That AndroGel was designed defectively;

k. That AndroGel was designed improperly.

138. Defendants were under a duty to disclose to Plaintiff and/or his physicians, hospitals, healthcare providers, and/or the FDA the defective nature of AndroGel.

139. Defendants had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects, and hence, cause damage to persons who used AndroGel, including the Plaintiff in particular.

140. Defendants' concealment and omissions of material facts concerning, *inter alia*, the safety of the use of AndroGel was made purposefully, willfully, wantonly, and/or recklessly, to mislead Plaintiff and/or his physicians, hospitals and/or healthcare providers into reliance, continued use of AndroGel, and actions thereon, and to cause them to purchase, recommend, and/or dispense AndroGel and/or use the products.

141. Defendants knew that Plaintiff and/or his physicians, hospitals, healthcare providers, and/or the FDA had no way to determine the truth behind Defendants' concealment and omissions, and that these included material omissions of facts surrounding AndroGel, as set forth herein.

142. Plaintiff, as well as their doctors, healthcare providers, and/or hospitals reasonably relied on facts revealed which negligently, fraudulently and/or purposefully did not include facts that were concealed and/or omitted by Defendants.

143. By reason of the foregoing Plaintiff has experienced and/or is at risk of experiencing serious and dangerous side effects including but not limited to, heart attacks, strokes, pulmonary embolisms, cardiovascular events and blood clots, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

144. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses.

145. By reason of the foregoing, Plaintiffs have been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

SEVENTH CAUSE OF ACTION
AS AGAINST ALL DEFENDANTS
(NEGLIGENT MISREPRESENTATION)

146. Plaintiffs repeat, reiterate and re-allege each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

147. Defendants had a duty to represent to the medical and healthcare community, and to the Plaintiff, the FDA and/or the public in general that AndroGel, had been tested and found to be safe and effective for its intended use as testosterone replacement therapy.

148. The representations made by Defendants were, in fact, false.

149. Defendants failed to exercise ordinary care in the representation of AndroGel, while involved in its manufacture, sale, testing, quality assurance, quality control, and/or distribution of said product into interstate commerce, in that Defendants negligently misrepresented AndroGel's high risk of unreasonable, dangerous side effects.

150. Defendants breached their duty in representing AndroGel's serious side effects to the medical and healthcare community, to the Plaintiff, the FDA and/or the public in general.

151. By reason of the foregoing Plaintiff has experienced and/or is at risk of experiencing serious and dangerous side effects including but not limited to, heart attacks,

strokes, pulmonary embolisms, cardiovascular events and blood clots, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

152. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

153. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

EIGHTH CAUSE OF ACTION
AS AGAINST ALL DEFENDANTS
(FRAUD AND DECEIT)

154. Plaintiffs repeat, reiterate and re-allege each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

155. Defendants conducted research and used AndroGel as part of their research.

156. As a result of Defendants' research and testing, or lack thereof, Defendants blatantly and intentionally distributed false information, including but not limited to assuring the public, the Plaintiff, his doctors, hospitals, healthcare professionals, and/or the FDA that the AndroGel was safe for their intended use.

157. As a result of Defendants' research and testing, or lack thereof, Defendants intentionally omitted certain results of testing and research to the public, healthcare professionals, and/or the FDA, including the Plaintiff.

158. Defendants had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public and the Plaintiff, as well as their healthcare providers and/or the FDA.

159. The information distributed to the public, the FDA, and the Plaintiff by Defendants, including but not limited to reports, press releases, advertising campaigns, television commercials, print ads, magazine ads, billboards, and all other commercial media contained material representations of fact and/or omissions.

160. The information distributed to the public, the FDA, and the Plaintiff by Defendants intentionally included representations that Defendants' AndroGel was safe for its intended use.

161. The information distributed to the public, the FDA, and the Plaintiff by Defendants intentionally included representations that Defendants' AndroGel carried the same risks, hazards, and/or dangers as other testosterone replacement products.

162. The information distributed to the public, the FDA, and the Plaintiff by Defendants intentionally included false representations that AndroGel was not injurious to the health and/or safety of its intended users.

163. These representations were all false and misleading.

164. Upon information and belief, Defendants intentionally suppressed, ignored and disregarded test results not favorable to the Defendants, and results that demonstrated that the AndroGel was not safe for use as testosterone replacement therapy.

165. Defendants intentionally made material representations to the FDA and/or the public, including the medical profession, and the Plaintiff regarding the safety of AndroGel, specifically but not limited to AndroGel not having dangerous and serious health and/or safety concerns.

166. Defendants intentionally made material representations to the FDA and/or the public in general, including the medical profession, and the Plaintiff regarding the safety of AndroGel.

167. That it was the purpose of Defendants in making these representations to deceive and defraud the public, the FDA, and/or the Plaintiff to gain the confidence of the public, healthcare professionals, the FDA, and/or the Plaintiff to falsely ensure the quality and fitness for use of AndroGel and induce the public, and/or the Plaintiff to purchase, request, dispense, recommend, implant and/or continue to use AndroGel.

168. Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff that AndroGel was fit and safe for use as testosterone replacement therapy.

169. Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff that AndroGel was fit and safe for use as testosterone replacement therapy and did not pose risks, dangers, or hazards above and beyond those identified and/or associated with other available analgesics.

170. That Defendants made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and the Plaintiff that AndroGel did not present serious health and/or safety risks.

171. That Defendants made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and the Plaintiff that AndroGel did not present health and/or safety risks greater than other available testosterone replacement products.

172. That these representations were false when made, and/or were made with a pretense of actual knowledge when knowledge did not actually exist, and/or were made recklessly and without regard to the actual facts.

173. That these representations and others, made by Defendants, were made with the intention of deceiving and defrauding the Plaintiff, his healthcare professionals and/or the FDA, and were made in order to induce the Plaintiff and/or his healthcare professionals to rely upon misrepresentations and caused the Plaintiff and/or his healthcare professionals to purchase, use, rely on, request, dispense, and/or recommend AndroGel.

174. That Defendants, recklessly and intentionally falsely represented the dangerous and serious health and/or safety concerns of AndroGel to the public at large, including the Plaintiff, for the purpose of influencing the marketing of a product known to be dangerous and defective and/or not as safe as other alternatives.

175. That Defendants willfully and intentionally failed to disclose the material facts regarding the dangerous and serious safety concerns of AndroGel by concealing and suppressing material facts regarding the dangerous and serious health and/or safety concerns of AndroGel.

176. That Defendants willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations with the purpose and design of deceiving and lulling the Plaintiff, as well as their healthcare professionals, into a sense of security so that Plaintiff would rely on the representations and purchase, use and rely on AndroGel and/or that his healthcare providers would dispense, prescribe and/or recommend the same.

177. Defendants, through their public relations efforts, which included but were not limited to the public statements and press releases, knew or should have known that the public, including the Plaintiff, as well as his healthcare professionals would rely upon the information being disseminated.

178. Defendants utilized direct to consumer adverting to market, promote, and/or advertise AndroGel.

179. That the Plaintiff and/or his healthcare professionals did in fact rely on and believe the Defendants' representations to be true at the time they were made and relied upon the representations as well as their superior knowledge of testosterone therapy and was thereby induced to purchase, use and rely on Defendants' AndroGel.

180. That at the time the representations were made, the Plaintiff and/or his healthcare providers did not know the truth with regard to the dangerous and serious health and/or safety concerns of AndroGel.

181. That the Plaintiff did not discover the dangerous and serious health and/or safety concerns and the false representations of Defendants nor could the Plaintiff, with reasonable diligence, have discovered the true facts.

182. That had the Plaintiff known the true facts with respect to the dangerous and serious health and/or safety concerns of AndroGel, Plaintiff would not have purchased, used and/or relied on Defendants' AndroGel.

183. That the Defendants' aforementioned conduct constitutes fraud and deceit, and was committed and/or perpetrated willfully, wantonly and/or purposefully on the Plaintiff.

184. By reason of the foregoing Plaintiff has experienced and/or is at risk of experiencing serious and dangerous side effects including but not limited to, heart attacks,

strokes, pulmonary embolisms, cardiovascular events and blood clots, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

185. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

186. By reason of the foregoing, Plaintiffs have been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00)

NINTH CAUSE OF ACTION FOR THE PLAINTIFF VICKIE DEFOREST AGAINST DEFENDANTS (LOSS OF CONSORTIUM)

187. Plaintiffs repeat, reiterate and re-allege each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

188. Plaintiff Vickie Deforest, was and is the lawful spouse of Plaintiff Jeffrey Deforest, and as such, was and is entitled to the comfort, enjoyment, society and services of her spouse.

189. As a direct and proximate result of the foregoing, Plaintiff Vickie Deforest**,** was deprived of the comfort and enjoyment of the services and society of his spouse, Plaintiff Jeffrey Deforest, and has suffered and will continue to suffer economic loss, and has otherwise been

emotionally and economically injured. The Plaintiff's injuries and damages are permanent and will continue into the future. The Plaintiffs seek actual and punitive damages from the Defendants as alleged herein.

190. For the reasons set forth herein, Plaintiff Vickie Deforest suffered and will continue to suffer the loss of her loved one's support, companionship, services, society, love and affection.

191. By reason of the foregoing, Plaintiff Vickie Deforest has been damaged by the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against the Defendants on each of the above-referenced claims and Causes of Action and as follows:

1. Awarding compensatory damages to Plaintiffs for past and future damages, including but not limited to pain and suffering for severe and permanent personal injuries sustained by the Plaintiffs, health care costs, medical monitoring, together with interest and costs as provided by law;

2. For any other causes of action and/or claims as may be compensable under local laws and/or statutes as may apply under the laws in the jurisdiction and venue in which this case will be transferred for trial;

3. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to the Plaintiffs in an amount sufficient to punish Defendants and deter future similar conduct;

4. Awarding Plaintiffs reasonable attorney's fees;

5. Awarding Plaintiffs the costs of these proceedings; and

6. Such other and further relief as this Court deems just and proper.

Dated: Chicago, Illinois
April 3, 2014

By: /s/ Roger C. Denton

Roger C. Denton, #06182610
Schlichter, Bogard & Denton, LLP
100 South Fourth Street, Ste 900
St. Louis, MO 63102
314-621-6115 (phone)
314-621-7151 (fax)

-and-

Douglas & London, P.C.
59 Maiden Lane, Suite 600
New York, New York 10038
Ph: (212) 566-7500
Fax: (212) 566-7501
Email: mlondon@douglasandlondon.com

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury as to all issues.

_____/s/ Roger C. Denton_____
ROGER C. DENTON